JUN 0 3 2013

Section 5 **510(k) SUMMARY** **Traditional 510K**

Submitter Information:

Submitter: MEDCOMP®
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Contact: Timothy Holwick, Regulatory Associate
Date Prepared: December 28, 2012

Device Name: Valved Tearaway Introducer Generation II
Common Name: Introducer, Catheter
Classification Name: Blood Access device and accessories (a)(2)(b)(2)
C.F.R. Section: 870.1340
Classification Panel: Cardiovascular
Class: II, DYB

Predicate Devices:
Primary:
K090394, Valved Tearaway Introducer Generation I, concurrence date September 1, 2009. Class II CFR 870.1340

Device Description:

The Medcomp Valved Tearaway Introducer is a two-part single use device used to obtain vascular access and facilitate intravascular catheter insertion. The Medcomp Valved Tearaway Introducer consists of a peel-able introducer sheath which contains a "duckbill" seal to substantially minimize air/blood from entering or escaping when the dilator is removed. The dilator is comprised of a cylindrical tube with a locking hub; the sheath is also a cylindrical tube with a hub and valve. When the dilator is fully seated it snaps into the hub of the introducer sheath to prevent independent movement of either piece when in use. The dilator extends beyond the sheath to provide a zero tolerance clearance between sheath and dilator. The sheath and dilator when used in conjunction with an introducer needle and guidewire provide a means to obtain a percutaneous opening to the vascular system to facilitate the insertion of a catheter. After removing the dilator a catheter can then be placed through the sheath. Breaking the sheath's hub and peeling the sheath away from the catheter then allows the sheath to be removed. The dilator is composed of Nylon-based Triax with Barium Sulfate for visibility under fluoroscopy by the attending physician during insertion. The sheath is composed of PTFE to provide a smooth, consistent peel.

Intended Used:

The Valved Tearaway Introducers are intended to obtain central venous access to facilitate catheter insertion into the central venous system.

Indications for Use:

The Valved Tearaway Introducers are intended to obtain central venous access to facilitate catheter insertion into the central venous system. The Valved Tearaway Introducer Generation II is designed to reduce blood loss and the risk of air intake but it is not a hemostasis valve. It is not intended to create a complete two-way seal nor is it intended for arterial use.

Comparison to Predicate Devices:

The Valved Tearaway Introducer Generation II is substantially equivalent to the predicate devices in terms of intended use, materials, anatomical location, basic design, performance, labeling, manufacturing process and method of sterilization.

Performance Standards:

Performance standards have not been established by the FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

Summary of Non-Clinical Performance Testing:

The following Performance – Bench Testing results and protocols are provided in this submission:

- Air Leakage
- Dilator Insertion/Extraction
- Force at Break
- Force at Break: Dilator Hub
- Liquid Leakage

All results can be found in Section 18. As illustrated with side-by-side testing results against the predicate device in the Section 12 Substantial Equivalence Matrix, the performance testing demonstrates that the proposed device exceeds all the testing criteria the predicate device was tested against. In addition, the matrix shows that the proposed device has comparable or improved results for many of the performance tests when compared to the predicate device.

Biocompatibility:

Results for all biocompatibility testing demonstrate the materials used meet the requirements of ISO 10993.

In Section 15 of this submission, a biocompatibility summary and test reports are provided. The following materials are identical to the predicate device (K090394) and therefore the biocompatibility testing for those components can be found in that submission:

- Sheath: Gray Teflon Tubing w/ 9% BiO3
- Valve: Silicone, C6-570
- Dilator Hub: HDPE
- Dilator Tube: Gray HDPE – Soltex K44-24-122 w/ BaSO4 and UV Stabilizer

The following remaining components were tested and the reports have been included in Section 15:

- Valved Peelable Snap Hub: Nylon/ABS (Triax)
- Snap Cap: Nylon/ABS (Triax)
- Colorants: Gray, Green, Orange and Lt. Blue

The testing provided, when read with the testing for relevant components of K090394, demonstrate that the materials used meet ISO 10993 requirements for limited contact external communicating device with indirect blood contact.

Technological Characteristics:

The principles of operation are the same as the predicate devices. There are no new questions raised regarding the safety or effectiveness of the device.

Summary of Substantial Equivalence:

The proposed device meets the performance criteria of design verification as specified by ISO standards, guidance documents and test protocols. The proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed device is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 3, 2013

Medcomp
c/o Timothy Holwick
Regulatory Associate
1499 Delp Drive
Harleysville, PA 19438

Re: K124046
Trade/Device Name: Valved Tearaway Introducer Generation II
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: May 2, 2013
Received: May 3, 2013

Dear Mr. Holwick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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Enclosure

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Indications for Use

510(k) Number (if known): K124046

Device Name: Valved Tearaway Introducer Generation II

Indications for Use:

The Valved Tearaway Introducers are intended to obtain central venous access to facilitate catheter insertion into the central venous system.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner

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